Remarks

Claims 1-52 are pending. The PTO requires the restriction of the claims in the above-identified application into one of the following three groups of claims.

Group I, claims 1-34 and 36, allegedly drawn to a method comprising introducing into the subject an antigen, collecting a tissue sample from the subject, and detecting the presence of VLA-1^{+}antigen-specific T cells;

Group II, claim 35, allegedly drawn to a method of treating a subject comprising administering to the subject an antigen to be identified; and

Group III, claims 37-52, allegedly drawn to a method of treating a subject with a disease comprising administering to the subject VLA-1^{+} antigen-specific T cells.

The Examiner has also required election of one species among each of the following groups is Group II is elected.

Species I: an election of one antigen species from claims 3, 6, 8, 10, and 12-14; Species II: an election of one tissue sample species from claims 15-18; Species III: an election of one collection period species from claims 20-25; Species IV an election of one subject species from claims 26-28; and Species V: an election of one measuring technique species from claims 29-31.

If Group III is elected, it is required that an election to elect one antigen species from claims 39, 42, 44, 46, 48, 50, and 51.

Applicants provisionally elect Group I (claims 1-34 and 36) with traverse. Applicants also provisionally elect the following species: Species I – wherein the antigen is influenza A (Claims 1-4 and 15-34 and 36); Species II – wherein the tissue sample is a pulmonary lavage (Claims 1-14, 16, and 19-34 and 36); Species III wherein the tissue sample is collected 6-10 days after the antigen introduction (Claims 1-20, and 26-34 and 36); Species IV wherein the subject is a human. (Claims 1-25 and 28-34 and 36); and Species V wherein the measuring technique is flow cytometry (Claims 1-28, 30-34 and 36).

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or

corresponding special technical features. The special technical feature must define a contribution that the claimed subject matter makes over the prior art.

Applicants note that the claims all include a detecting the presence of or administering VLA-1+ (positive) antigen-specific T cells, and that this limitation constitutes a special technical feature that defines a contribution that the claimed subject matter makes over the prior art. Thus, the pending claims all have the same corresponding technical feature. Applicants respectfully remind the Examiner that PCT Rule 13.2 states that:

> the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Additionally, MPEP 1850 states that contributions over the prior art "should be considered with respect to novelty and inventive step." Applicants respectfully point that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy single the inventive concept. Moreover, the Examiner has provided no evidentiary basis for her assertion that the present claims do not share this common technical feature. Accordingly, a lack of unity rejection based on the search report is not valid. Thus, the Examiner has not met his burden for establishing a lack of unity of invention. Moreover, Applicants respectfully point out that the VLA-1+ (positive) antigen-specific T cells are an integral part of each of the present claims and the methods claimed herein can not be practiced as claimed without said cells. Accordingly, Applicants submit that for this reason at least pending Claims 1-34 and 36 (Group I), Claim 35 (Group II), and Claims 37-52 (Group III) possess unity of invention and restriction is improper.

Regarding the species elections, Applicants respectfully point out that as discussed in the 37 C.F.R. § 1.141(a), an application may claim a reasonable number of species within a claimed genus as long as at least one genus claim encompassing all of the species is patentable. The Examiner has indicated that a *specific* species of each of the 5 groups must be elected. Applicants assert that this is not an appropriate application of the 37 C.F.R. § 1.141, which is aimed at situations where there are unreasonable numbers of species claimed. The present situation is not a situation where the applicants are claiming a genus of compounds, for example,

a set of 1000 different nucleic acid molecules, and also claiming each of the encompassed species separately, which would be an appropriate circumstance for application of the election of species requirement. Rather, applicants have claimed in each genus a small number of species possibilities. Applicants are not required in the present application to elect a species when applicants have not claimed an unreasonable number of species.

Moreover, Applicant would like to specifically and respectfully point out that with respect to the detection methods of species group IV, a tetramer is a particular type of detectable entity akin to an antibody which is visualized via immunohistochemistry or flow cytometry. A tetramer can not be used apart from these techniques. Therefore, a search conducted for flow cytometry would necessarily include tetramers which are visualized using this technique.

Applicants believe that they have shown the species election to be unreasonable. Applicants further recognize that Claims 1, 34, 36, and 37 have been acknowledged by the Examiner as being generic. Thus, when a genus claim is found to be patentable, Applicants understand that the remaining members of the reasonable number of species must be examined.

For the reasons stated above, applicants respectfully assert that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the Patent Office and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Examining all of the claims together would eliminate the necessity of prosecuting multiple, separate, yet intimately related, applications. Thus, applicants respectfully request that all of the claims of this application be examined together. Consequently, reconsideration and modification or withdrawal of the restriction requirement is requested.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A Credit Card Payment authorizing payment in the amount of $1,175.00 which is the small entity fee under 37 C.F.R. § 1.17(a)(5) for a five (5) month extension of time, and a Request for a five (5) month Extension of Time are being submitted electronically. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.

/J. Gibson Lanier, Ph.D., 57,519/ — J. Gibson Lanier, Ph.D.

February 8, 2010 — Date